

## Okada Purifying Therapy in Refractory Migraine: A Pilot Study

Gianluca BRUTI<sup>1</sup> and Manuela RAMOS Atencio<sup>2</sup>

### Abstract

**Objectives:** 1) To evaluate the efficacy of Okada Purifying Therapy (OPT) in the reduction of disability, intensity of pain and psychological distress of migraine patients refractory to pharmacological preventive treatment; 2) To determine the therapeutic effect of OPT on muscle tenderness of cranio-cervico-mandibular district in migraine patients.

**Methods:** According to International Headache Society (IHS, 2004), we consecutively recruited 18 migraine patients non responders to prophylaxis drugs. During a 2 months period, a total of 16 OPT sessions was performed to each patient. At the entry of the study and after 1 month from the last OPT session the following clinical measures were obtained and compared: MIgraine Disability ASsessment (MIDAS), Headache Impact Test – 6 items (HIT-6), and both numeric and semantic pain intensity scales; Beck Depression Inventory (BDI), Rome Depression Inventory (RDI) and State and Trait Anxiety Inventory (STAI); Tenderness Total Score (TTS), number of systemic Tender Points (TPs) and the Physical Examination of the Cervical Spine (PECS).

**Results:** OPT significantly reduced MIDAS, HIT-6 and intensity of pain scores of migraine patients ( $p=0.003$ ,  $p=0.002$ , and  $p=0.002$  respectively) as well as TTS, PECS scores and TPs number ( $p=0.02$ ,  $p=0.06$ , and  $p=0.02$  respectively). A reduction of depressive and anxiety symptoms were also observed by means of BDI, RDI and STAI respectively ( $p=0.004$ ,  $p=0.004$ ,  $p=0.003$  for STAI-1 and  $p=0.002$  for STAI-2 respectively).

**Conclusions:** OPT may represent a useful clinical approach to reduce disability, muscle tenderness and psychological distress in non responders to preventive drugs among migraine patients. Further studies with more large sample size have to be performed exploring the OPT relaxation effect on pericranial and cervical muscles in migraine patients.

### Keywords:

Okada Purifying Therapy, migraine, muscle tenderness, pain, MIDAS

### Introduction

Migraine is a heterogeneous chronic neurovascular disorder characterized by recurring attacks of severe headache and autonomic neurological symptoms<sup>1</sup>. It is a major source of morbidity in the Western countries<sup>2</sup>.

Noncompliance or nonadherence with medical regimens represents a major challenge to the practice of medicine

including the treatment of headache. Indeed, medication use patterns are particularly relevant to headache because of the potential for headache therapies to induce medication-overuse headache.

Previous research has demonstrated that adherence to long-term medication therapy for various chronic illnesses averages only about 50%. The rate of adherence among headache patients has been found to be similarly poor.

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<sup>1</sup>Department of Neurological Sciences, "Sapienza", University of Rome, Umberto I Policlinico di Roma, Viale del Policlinico, Codigo Postal 155-00161, Paviglione di Chirurgia Massilo-facciale, Roma, Italia. <sup>2</sup>MOA Italia, Via dei Buonvisi 61R, CAP 00148, Roma, Italia.

Corresponding Author: Dr. Gianluca Bruti, TEL: (+39)06-4997-9117, E-mail: gianluca.bruti@gmail.com

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Misuse or overuse of symptomatic medication has been demonstrated to contribute to treatment failure, and one-fourth to one-half of patients are noncompliant with prophylactic headache medications and at least 40% nonadherent with appointment-keeping. Adherence declines with more frequent and complex dosing regimens, side effects, and costs, and is subject to a wide range of psychosocial influences<sup>3,4</sup>. In this regard although effective drug treatments are available, they are not available to a substantial portion of patients due to medical contraindications (e.g., poor tolerance, pregnancy). In addition, long-term prevention through prophylactic medication is a major problem. Confronted with such limitations of drug treatments patients and health care providers consider behavioral treatments as an alternative or an addition to pharmacological treatments<sup>4</sup>.

Nowadays a relevant proportion of patients prefer non-pharmacologic or complementary therapies. In Italy as well as in other many countries homeopathy, herbal remedies and particularly acupuncture are the most widely used complementary therapies.

Okada Purifying Therapy (OPT)<sup>5</sup> represents a non pharmacological treatment which promotes health of mind and body by intensifying the natural self-healing ability innate in human beings. In this view stiff, warm and/or tender spots on the body are considered important clinical targets in upgrading natural self-healing abilities. In fact OPT is important to identify the sites of these “hot” and pain points in each patient to radiate the energy toward these affected areas.

Up to date to our knowledge there are no OPT practitioners in Italy except for one of the two authors of the present work (M. R. A.). Moreover, up to date, there are no published studies in the world on the efficacy of OPT in pain syndromes such as migraine.

It is interesting to note that in Occidental medicine Tender Points (TPs) examination represents an important clinical step as well, particularly for fibromyalgia diagnosis and cervicogenic headache treatment<sup>6,7</sup>.

For the above mentioned issues the main aim of this

study was to evaluate the efficacy of OPT in the reduction of disability, muscles tenderness and psychological distress in migraine patients who do not respond to common preventive drugs for migraine.

## Methods

The patients included in the study were selected among subjects who have been consecutively admitted our headache section of Borzomati Pain Center, Policlinico Umberto I, “Sapienza” University of Rome, Italy. According to the IHS criteria (2004)<sup>7</sup>, after a well explanation about the significance of OPT and obtained an informed consent, we recruited migraine patients with and without tension type headache and excluded patients presenting with other types of headache, as well as those who had taken prophylaxis therapy in the three months prior to enrolment.

Any clinically relevant psychiatric disorder was excluded by means of a semistructured interview based on a symptoms checklist elaborated according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria<sup>8</sup>.

In Table 1 are reported the inclusion criteria of the sample study.

To evaluate the clinical pattern of the sample study, a standardized clinical interview has been administered to each patient before and after OPT (Table 1). Moreover the same clinical variables have been collected by the means data reported in the diary of the three months prior to enrolment and the means data registered during the 2 months of OPT and 1 month after the last OPT session. We decided to compare the baseline clinical scores with those observed after 1 month the last OPT session, to evaluate the efficacy of treatment relatively off from the main effects of OPT period. This to exclude any clinical placebo effect link to the single OPT session per se and in the same time to explore the long term OPT efficacy.

Intensity of pain has been evaluated using a 10-point Numeric Pain Intensity Scale (NPIS).

**Table 1. Inclusion criteria of the sample study and clinical items included into standardized history submitted to all migraine patients.**

Inclusion Criteria	Clinical Items
1) Age ranging from 18 to 55 years	1) Age at headache onset
2) Informed consent	2) *MIDAS
3) More than 2 migraine crises per month	3) **HIT-6
4) Refractory migraine to traditional drugs for preventive treatment (3 consecutive pharmacological attempts).	4) Intensity of headache: 4 level semantic and behavioural scale
5) No overuse of symptomatic medication	5) Intensity of headache: ***NPIS (see below)
6) No pharmacological preventive therapy	
7) Patients studied during the interictal phase	
8) No history of major psychiatric disorders (e.g. bipolar disorder, major depressive disorder)	

\*Migraine Disability Assessment Scale, \*\*Headache Impact Test – 6 items, \*\*\*Numeric Pain Intensity Scale

To evaluate migraine disability, Migraine Disability Assessment Scale (MIDAS)<sup>9)</sup> and Headache Impact Test 6 items (HIT-6)<sup>10, 11)</sup> have been also administered before and after treatment.

MIDAS is a self-administered questionnaire translated and validated in several countries. It includes five disability-related questions covering the previous 3-month period. Patients score the number of lost days due to headache in three domains, which are school or paid work; household work; family, social, or leisure activities. They also report the number of additional days with significant limitations of activity (defined as at least 50% reduced productivity) in the paid work and household work domains. The MIDAS score is sum of the scores of these five questions. The two additional questions (A and B) are not scored, but provide the physician with clinically relevant information (Appendix).

Italian MIDAS version has a good internal consistency (Cronbach's alpha 0.7) with good test-retest reliability (Spearman's correlation 0.77), closely similar to that found in English-speaking migraineurs supporting the use of the MIDAS questionnaire as a clinical and research tool in Italian patients<sup>9)</sup>.

The HIT-6 is a brief self-administered questionnaire designed to assess the impact of headaches from the patient's perspective. The scale consisted of six items that

cover various content areas reflected in health-related quality of life: pain, social functioning, role functioning, vitality, cognitive functioning, and psychological distress. Each of the six questions is responded to using one of five response categories: "never," "rarely," "sometimes," "very often," or "always." For each item, 6, 8, 10, 11, or 13 points, respectively, are assigned to the response provided. These points are summed to produce a total HIT-6 score that ranges from 36 to 78. Higher scores indicate a greater impact of headaches on the daily life of a respondent. Scores can be interpreted using four groupings that indicate the severity of headache impact on the patient's life, with scores of 49 points or fewer reflecting "little or no impact," scores of 50 to 55 points reflecting "some impact," scores of 56 to 59 reflecting "substantial impact," and scores of 60 or more points reflecting "severe impact."

For the evaluation of depressive state and anxiety, the Beck Depression Inventory (BDI)<sup>12)</sup>, the Rome Depression Inventory (RDI)<sup>13)</sup> and the State and Trait Anxiety Inventory (STAI 1-2)<sup>14)</sup> have been respectively administered to all subjects at the time of enrolment and at the end of the study.

The BDI is a self administered 21-item rating scale (range 0–63). Scores were regarded as a continuous variable or divided into four groups: 0–9=normal mood; 10–18=mood ranging from mild to moderate depression; 19–29=

mood ranging from moderate to severe depression; and 30–63= severe depression<sup>12)</sup>.

The RDI<sup>13)</sup> was used to assess the depressive state of the subjects; it is a 25-items self rating scale with a high reliability. It is also an instrument particularly suited to an Italian sample because it is based on the most frequent statements recorded in clinical notes as they have been reported by patients with depression. Therefore the peculiarity of this scale lies in the fact that construction and validation were conducted directly on an Italian population, unlike other self-rating instruments translated into Italian. Individuals respond to a four-point scale: never, sometimes, often, almost always. Mean reference values are  $33 \pm 6.3$  for men and  $39.4 \pm 12.1$  for women. Scores superiors to these reference values suggest the presence of a depressive state.

The STAI<sup>14)</sup> is probably amongst the most widely used self-report measures of anxiety in clinical and research settings. STAI is a self-report scale measuring two separate components: state anxiety, which refers to a transitory emotional state characterised by subjective feelings of tension that may vary in intensity over time, and trait anxiety, which refers to a relatively stable disposition to respond to stress with anxiety and a tendency to perceive a wider range of situations as threatening ones. The scores of this trait form varied between 20 and 80 (the higher the score is, the worse the symptoms of anxiety are).

In order to evaluate the tenderness of craniomandibular and cervical muscles, in addition to the neurological examination, all subjects have been evaluated by means of Tenderness Total Score (TTS)<sup>15)</sup> and the Physical Examination of the Cervical Spine (PECS) including items that belong to the diagnostic criteria for cervicogenic headache<sup>16)</sup>.

Moreover for the evaluation of systemic TPs we have utilized the topographic map for the diagnosis of fibromyalgia<sup>6)</sup> (Figure 1). All examinations of muscle tenderness were performed.

In Table 2 are listed the clinical and psychometric variables considered in the statistical analysis.

**Table 2. Clinical and psychometric variables considered in the statistical analysis.**

1) Migraine Disability Assessment
2) Headache Impact Test 6 items
3) Intensity of headache: 4 level semantic and behavioural scale
4) Intensity of headache: NPIS (see above in the method section)
5) Tenderness Total Score
6) Physical Examination of the Cervical Spine
7) Craniomandibular Index
8) Number of Tender Points
9) State and Trait Anxiety Inventory 1
10) State and Trait Anxiety Inventory 2
11) Beck Depression Inventory
12) Rome Depression Inventory

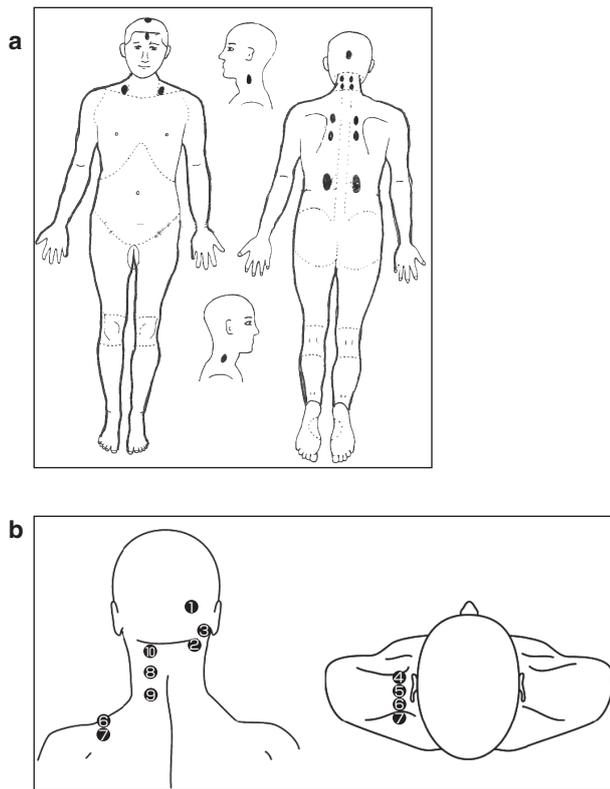
### Okada Purifying Therapy (OPT)

All patients have been invited to sit comfortably facing a practitioner. The energy has been directed to each patient towards forehead, upper chest and abdominal area from the front for five to ten minutes. Moreover in each patient, the energy has been directed from the top to the center of the head and down the spine; then to the back of the head and on to the left, then right shoulders.

In regards of the clinical evaluation of TrigeminoCervical Complex (TCC) structures and theirs relative temperature, a particular attention has been done on cervical nerves, zygapophyseal joints and others important structures such as trapezius and sternocleidomastoid muscles (Figure 1).

Together with these points applications, the OPT has been also concentrated on the kidney zones by the fact that kidney function level represents the most important component for the human purification in the Okada theory.

Each subject has been treated with two OPT sessions per week for a total of 16 treatments over a period of 8 weeks. All OPT session were performed by a single well trained certified practitioner for a period of 40 minutes (Table 3).



**Figure 1. Specific “hot spots” considered in the OPT<sup>5)</sup> (a), and spots of the Physical Examination of the Cervical Spine (b). b: In the OPT, 1 in the Occipital; 2 and 3 in the Medulla oblongata; 4, 5, 6 and 7 in the Shoulder; 8, 9 and 10 in the Nape.**

**Table 3. OPT protocol performed in each migraine patient.**

Number of patients	18
Duration of single session	40 minutes
Frequency of session	2 for week
Total number of session	16
Period of treatment	2 months

**Table 4. Demographics features of the study population.**

	Number of patients	Min	Max	Mean	Standard deviation
Gender (female/male ratio)	15/3				
Age	18	22	54	34.9	8.3
Education (yrs)	18	8	13	12.3	1.6
Illness duration (yrs)	18	1	32	14.2	9.0

**Table 5. Clinical diagnosis according to the International Headache Society Criteria (2004)<sup>7)</sup>.**

migraine without aura	migraine with and without aura	migraine without aura plus chronic tension type headache
3	2	13

## Statistical analysis

Statistical analyses have been performed by means of Wilcoxon signed-rank test for independent samples. The values of  $p < 0.05$  have been considered statistically significant. All analyses have been performed using the Statistics/Data Analysis (STATA, version 11.0).

## Primary and secondary end points and study design

By the fact that OPT represents an holistic model of the human medicine, the primary end points of this study was the reduction of migraine disability together with intensity of migraine pain as well as its psychological distress. The reduction of muscle tenderness of cranio-cervico-mandibular regions and the number of systemic TPs have been considered as secondary end points.

## Results

Eighteen migraine patients have been consecutively recruited among patients admitted to our pain clinic for headache complaint. The demographics features of sample are reported in Table 4.

According to IHS criteria (2004)<sup>7)</sup>, out of 18 migraineurs, 13 met the diagnosis of mixed headache (migraine plus tension type headache) (Table 5).

In the next Tables are reported the comparisons between the clinical scores observed at baseline evaluation and the scores observed at 3 months from the first OPT session (1

month after the last OPT treatment; see also in the methods section).

From clinical point of view, a significantly reduction of migraine disability has been observed after OPT as suggested by MIDAS and HIT-6 scores reduction (Table 6, Figure 2). For the too small sample of patients included in

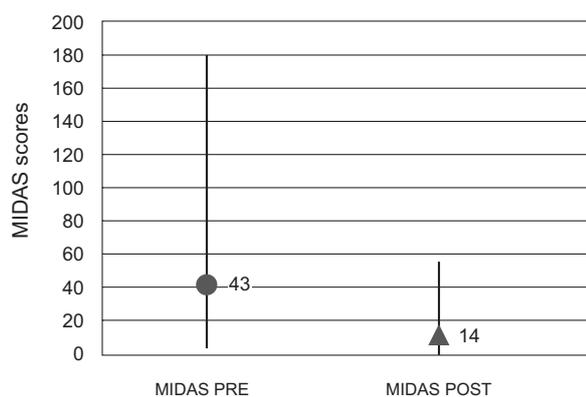
each group of grade disability, we decided not to perform any statistical analysis on the effect of OPT on MIDAS grade (for the description of MIDAS see methods section and Appendix).

A significant clinical improvement has been also observed in pain intensity variable (Table 6, Figure 3).

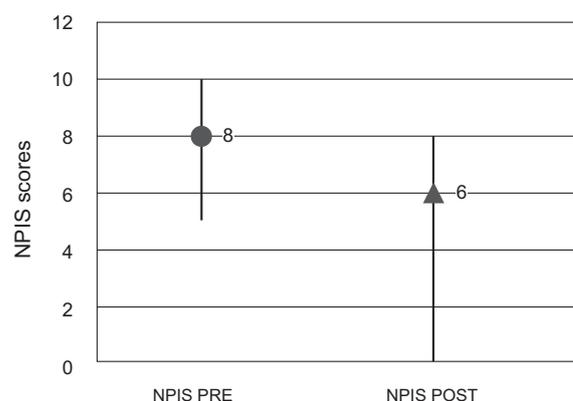
**Table 6. Migraine disability and intensity before and after OPT.**

	Evaluation time	Number of patients	Mean	Standard deviation	Median	Max	Min	p value
MIDAS score	Pre-treatment	18	52.6	47.6	43	180	3	p=0.003
	Post-treatment	18	16.5	15.6	14	55	0	
HIT-6	Pre-treatment	18	63.3	20.1	64	78	48	p=0.002
	Post-treatment	18	52.9	6.6	50	65	42	
NPIS	Pre-treatment	18	8.4	1.4	8	10	5	p=0.002
	Post-treatment	18	5.5	2.4	6	8	0	

List of abbreviations. MIDAS: Migraine Disability Assessment Scale, HIT-6: Headache Impact Test (6 items), NPIS: Numeric Pain Intensity Scale.



**Figure 2. MIDAS scores median before and after OPT treatment. Median (circle = pre; triangle = post) and min-max values.**

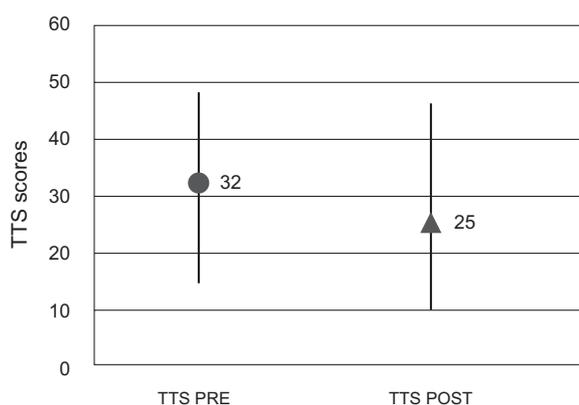


**Figure 3. NPIS scores median before and after OPT treatment. Median (circle = pre; triangle = post) and min-max values.**

**Table 7. Muscle tenderness level of pericranial and cervical regions and number of systemic TPs before and after OPT.**

	Evaluation time	Number of patients	Mean	Standard deviation	Median	Max	Min	p value
TTS	Pre-treatment	18	30.3	8.9	32	48	15	p=0.02
	Post-treatment	18	27.4	11.4	25	46	10	
PECS	Pre-treatment	18	13.0	0.13	14	20	7	p=0.06
	Post-treatment	18	12.7	0.14	13	20	5	
TPs	Pre-treatment	18	11.3	0.16	11	17	6	p=0.02
	Post-treatment	18	10.0	0.21	10	16	3	

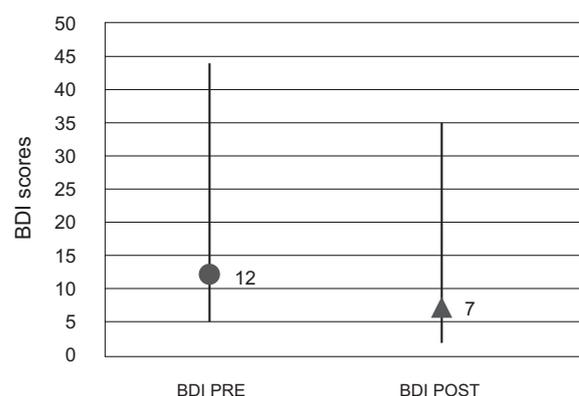
List of abbreviations. TTS: Tenderness Total Score, PECS: Physical Examination of the Cervical Spine, TPs: Tender Points (number).



**Figure 4. TTS scores median before and after OPT treatment.** Median (circle = pre; triangle = post) and min-max values.

In respect of muscle tenderness, after OPT we observed a significant reduction of TTS and TPs number (Table 7, Figure 4).

Finally we observed an improvement with a significant level in all psychometric scales scores after OPT treatment (Table 8, Figure 5). For the too small sample of patients included in each group of BDI severity, we decided not to perform any statistical analysis on the effect of OPT on depressive grade measured by means of BDI scores (for the description of BDI see methods section). In the same way, for the statistical analysis, we did not consider the cut-off of RDI to evaluate the presence/absence of depressive state (for the description and cut-off of RDI see methods section).



**Figure 5. BDI scores median before and after OPT treatment.** Median (circle = pre; triangle = post) and min-max values.

## Discussion

To our knowledge, this is the first attempt investigating the efficacy of OPT on migraine syndrome.

A reduction of migraine disability associated with the intensity of pain after OPT was the main principal results observed in the present study. The importance of these findings appears much more evident if we consider the resistance of our sample study to preventive pharmacological drugs for migraine.

In particular OPT significantly reduced both MIDAS and HIT-6 scores in migraine patients. Although these scales are able to measure headache-related disability in a similar fashion, MIDAS seems to be influenced by migraine

**Table 8. Psychometric evaluation before and after OPT.**

	Evaluation time	Number of patients	Mean	Standard deviation	Median	Max	Min	p value
BDI	Pre-treatment	18	16.6	12.3	12	44	5	p=0.004
	Post-treatment	18	10.4	9.5	7	35	2	
RDI	Pre-treatment	18	46.7	13.3	42	82	30	p=0.004
	Post-treatment	18	38.2	8.7	35	57	28	
STAI-1	Pre-treatment	18	48.0	14.3	43	74	32	p=0.002
	Post-treatment	18	41.0	13.0	35	70	28	
STAI-2	Pre-treatment	18	49.2	11.5	44	71	31	p=0.003
	Post-treatment	18	43.2	11.4	35	66	26	

List of abbreviations. BDI: Beck Depression Inventory, RDI: Rome Depression Inventory, STAI-1: State and Trait Anxiety Inventory (items for anxiety state evaluation), STAI-2: State and Trait Anxiety Inventory (items for anxiety trait evaluation).

frequency whilst HIT-6 appears to be more correlated with intensity of headache pain<sup>17)</sup>. For this reason it has been suggested that the combined use of these two migraine scales may give a more accurate assessment of patient's headache-related disability<sup>17)</sup>. On the other hand we also observed a significant reduction of intensity of pain in migraine patients treated with OPT. The results indirectly support the positive clinical correlation between disability and intensity of pain in migraine patients as well as the global clinical benefit of OPT in migraine syndrome.

Positive clinical effect of OPT in migraine is also supported by the reduction of pericranial and cervical tenderness and TPs number as observed in our sample. These data may justify per se the improvement of migraine disability. In fact high muscle tenderness of cranio-cervical district as well as the mixed headache type and psychiatric comorbidity has been found associated with more headache disability and migraine chronification<sup>18, 19)</sup>.

The results also showed a clinical efficacy of OPT in reducing depressive and anxiety scores in migraine patients. In this regard it has been found positive clinical inter-relationships between both MIDAS and HIT-6 and BDI scores<sup>17)</sup>. Then the improvement of psychological state together with the reduction of craniocervical muscle tenderness and systemic TPs number may explain the reduction of MIDAS and HIT-6 scores observed in the migraine patients after OPT.

The small number of sample together with a short follow up period and the lack of a control group (active drug or placebo design) are the most important limitation of the present pilot study.

Further studies have to be performed to support our findings and to explain in a neurophysiologic and/or neuroimaging fashion the mechanisms underlying the benefit effect of OPT on migraine patients.

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### Appendix. MIDAS questionnaire.

INSTRUCTIONS: Please answer the following questions about ALL your headaches you have had over the last 3 months.

Write your answer in the box next to each question. Write zero if you did not do the activity in the last 3 months.

- 1) On how many days in the last 3 months did you miss work or school because of your headaches?  
Number of days =
- 2) How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (Do not include days you counted in question 1 where you missed work or school) Number of days =
- 3) On how many days in the last 3 months did you not do household work because of your headaches?  
Number of days =
- 4) How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted in question 3 where you did not do household work) Number of days =
- 5) On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches? Number of days =

TOTAL days =

- A) On how many days in the last 3 months did you have a headache? (If a headache lasted more than 1 day, count each day) Number of days =
- B) On a scale of 0–10, on average how painful were these headaches? (Where 0 = no pain at all, and 10 = pain as bad as it can be)

Grading system for the MIDAS Questionnaire:

	Grade	Definition	Score
I	Little or no disability		0–5
II	Mild disability		6–10
III	Moderate disability		11–20
IV	Severe disability		21+

## 慢性偏頭痛における岡田式浄化療法の効果：予備調査研究

ジャンルカ・ブルティ<sup>1</sup> マヌエラ・ラモス・アテンチョ<sup>2</sup>

### 抄 録

**目的：**1) 薬理的予防治療が困難な偏頭痛患者において活動への障害、痛みの強さ、精神的苦痛を低減させる岡田式浄化療法 (OPT) の効果の評価、2) OPTが偏頭痛患者における頭部-頸部-下顎部の筋肉圧痛度に与える治療効果の確認。

**方法：**国際頭痛学会 (IHS, 2004) に従い、予防薬の効かない偏頭痛患者18名を被験者とした。それぞれの被験者には、2か月間に合計16回のOPT施術が行われた。初回の前と最終回の1か月後、以下の臨床データが得られ、解析が行われた：偏頭痛障害評価 (MIDAS)、頭痛インパクトテスト (HIT-6)、疼痛度の尺度；ベック抑うつ評価票 (BDI)、ローマ抑うつ評価票 (RDI) 状態不安と特性不安の調査票 (STAI)；圧痛総スコア (TTS)、圧痛点の数 (TPs)、後頸部の理学的検査 (PECS)。

**結果：**OPT施術により、MIDAS、HIT-6、痛みのスコアでは有意な数値低下が認められた (それぞれ  $p=0.003$ ,  $p=0.002$ ,  $p=0.002$ )。また、TTS、PECS、TPs数も同様であった (それぞれ  $p=0.02$ ,  $p=0.06$ ,  $p=0.02$ )。抑うつと不安の症状に関する低減についても、BDI、RDI、STAIで観察された (それぞれ  $p=0.004$ ,  $p=0.004$ , STAI-1で  $p=0.003$ ならびにSTAI-2で  $p=0.002$ )。

**結論：**OPTは、偏頭痛に効くとされる予防薬が効かない患者に対して、偏頭痛に起因する障害や筋肉の圧痛、精神的苦痛を緩和するために有効な臨床的方法であると考えられる。より大規模なサンプル数の研究を実施し、偏頭痛患者の頭部周辺および頸部の筋肉に対するOPTのリラクゼーション効果を調査することが必要である。

### キーワード

岡田式浄化療法、偏頭痛、筋肉圧痛度、痛み、MIDAS

<sup>1</sup>ローマ大学サピエンツァ校神経科学部

<sup>2</sup>MOAイタリア

連絡先：

ジャンルカ・ブルティ. TEL: (+39) 06-4997-9117,

E-mail: gianluca.bruti@gmail.com

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